K020781

page 1 of 2

MAY 0 6 2002

510(k) Summary

Device Trade Name: KCI Wound Cell Transparent Wound Dressing

Classification Name: Occlusive Wound Dressing (21 CFR 878.4020)

510(k) Applicant: Kinetic Concepts, Inc. (KCI)
8023 Vantage Drive
San Antonio, TX 78265-8508
Contact: Judith Harbour 1-800-275-4524

Predicate Devices: KCI Wound Cell Transparent Wound Dressing [510(k) Exempt]
KCI Wet Cell Transparent Wound Dressing [510(k) Exempt]
SimpliCare Transparent Wound Dressing (K991214)
Innovative Technologies' Transparent Film Dressing (K973312)

FDA Regulatory Status:

A final order published in the October 5, 1999 Federal Register exempted occlusive wound dressing from the premarket notification requirements when intended to cover a wound, provide or support a moist wound environment, and allow the exchange of gases such as oxygen and water vapor through the device. This classification regulation does not include occlusive wound dressings that contain added drugs or are composed of materials derived from animal sources.

Indication for Use:

FDA review of previous KCI 510(k) submissions for the KCI Wet Cell and Wound Cell Transparent Wound Dressings determined that both were exempt from the 510(k) requirements. Their indications for use are similar to the cited predicate devices (SimpliCare Transparent Wound Dressing and Innovative Technologies' Transparent Wound Dressings) granted FDA marketing clearance before the 510(k) exemption went into effect. They are intended to cover a wound, provide or support a moist wound environment, and allow the exchange of gases through the device. In addition, they may be used as a secondary fixation device for other wound care products such as alginates, gels and foams. The KCI occlusive wound dressings differ in that the Wound Cell includes an injection port. This injection port facilitates the application of topical wound care products after the wound dressing has been placed over the wound to serve as a secondary fixation device in addition to its other intended uses.

The KCI Wound Cell Transparent Dressing is intended to provide a moist wound healing environment to facilitate the normal wound healing process. The Wound Cell Dressing may also be used as a secondary fixation device for other topical wound treatment products such as antimicrobial and enzymatic debriding solutions and suspensions, alginates, gels and foams.

Purpose of This 510(k) Submission:

Labeling revision to provide directions for using a sterile syringe with an appropriately gauged needle to topically apply legally marketed topical wound treatment solutions, suspensions, alginates, gels and foams on the treatment site through the injection port of a previously applied KCI Wound Cell Transparent Wound Dressing.

Substantial Equivalence:

The FDA review of the previous 510(k) notification for the KCI Wound Cell Transparent Wound Dressing with the injection port for introducing sterile saline, alginates, gels and foams determined that this occlusive wound dressing was exempt from the 510(k) requirements. The present 510(k) submission for the labeling revisions also includes the labeling for several legally marketed topical wound treatment drugs (antimicrobial agent and debriding ointments). The revised labeling does not constitute a major change or modification in the intended use of the KCI Wound Cell Transparent Wound Dressing. No changes in the technological characteristics of this device were necessitated by this labeling revision. Applying the topical wound treatment drugs in this manner does not result in a change in their route of administration, dosage, or intended use. KCI concludes that the KCI Wound Cell Transparent Wound Dressing, as modified by this revised labeling, is substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2002

Kinetic Concepts, Inc.
Ms. Judith A. Harbour
8023 Vantage Drive
San Antonio, Texas 78230-4726

Re: K020781
Trade Name: KCI Wound Cell Transparent Wound Dressing
Regulation Number: 878.4020
Regulation Name: Occlusive wound dressing
Regulatory Class: I
Product Code: NAD
Dated: February 28, 2002
Received: March 11, 2002

Dear Ms. Harbour:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020781

Device Name: **The Wound Cell**

Indications For Use:

The KCI Wound Cell Transparent Dressing is intended to provide a moist wound healing environment to facilitate the normal wound healing process. The Dressing may also be used as a secondary fixation device for other topical wound treatments such as antimicrobial and enzymatic debriding solutions and suspensions, alginates, gels and foams.

The KCI Wound Cell Transparent Dressing is indicated for:

- Non-exudating to minimally exuding wounds
- Pressure sores
- Lacerations/abrasions
- Partial and full thickness wounds
- Surgical incisions
- Second degree burns
- Donor sites
- IV sites

CAUTION: Federal law restricts this device to sale by or on the order of a physician.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020781